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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

RENNER *et al.*

Appl. No. 09/275,883

Filed: March 25, 1999

For: **Inducible Alphaviral Gene
Expression System**



Art Unit: 1643

Examiner: To Be Assigned

Atty. Docket: 1700.0020001/JAG/SGW

Information Disclosure Statement

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each of these documents is provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

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RENNER *et al.*
Appl. No. 09/275,883

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Stephen G. Whiteside
Attorney for Applicants
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Date: 6/28/99

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1700-002001/JAG/SGW

APPLICATION NO.
09/275,883

APPLICANT
Renner et al.

FILING DATE
March 25, 1999

GROUP
1643

U. S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA1		5,532,154	07/02/1996	Brown, D. T.	435	235.1	03/21/1994
AB1		5,578,473	11/26/1996	Palese, P. et al.	435	172.3	03/10/1994
AC1		5,580,859	12/03/1996	Felgner, P. L. et al.	514	44	03/18/1994
AD1		5,705,163	01/06/1998	Pastan, I. et al.	424	260.1	06/05/1995
AE1		5,756,349	05/26/1998	Lin, F.-K.	435	325	06/06/1995
AF1		5,789,245	08/04/1998	Dubensky, Jr., T. W. et al.	435	320.1	10/30/1996
AG1		5,814,482	09/29/1998	Dubensky, Jr., T. W. et al.	435	69.3	10/30/1996
AH1		5,843,723	12/01/1998	Dubensky, Jr., T. W. et al.	435	69.3	10/30/1996
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL1		WO 97/38087	10/16/1997	WIPO			Yes No
AM1		EP 0 716 148 A2	06/12/1996	Europe			Yes No
AN1		WO 96/17072	06/06/1996	WIPO			Yes No
AO							Yes No
AP							Yes No

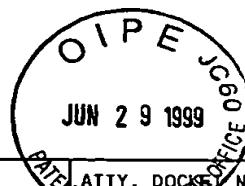
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	Altman-Hamamdzic, S. et al., "Expression of β -galactosidase in mouse brain: utilization of a novel nonreplicative Sindbis virus vector as a neuronal gene delivery system." <i>Gene Therapy</i> 4:815-822 (August 1997)
AS	1	Artelt, P. et al., "Vectors for efficient expression in mammalian fibroblastoid, myeloid and lymphoid cells via transfection or infection," <i>Gene</i> 68:213-219 (1988)
AT	1	Artuc, M. et al., "Differential promoter activity in benign and malignant human cells of skin origin," <i>Exp. Dermatol.</i> 4:317-321 (1995)

EXAMINER

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Barton, D. J. et al., "Demonstration In Vitro of Temperature-Sensitive Elongation of RNA in Sindbis Virus Mutant ts6," <i>J. Virol.</i> 62:3597-3602 (1988)
	AS	2	Bechler, K., "Influence of Capping and Polyadenylation on mRNA Expression and on Antisense RNA Mediated Inhibition of Gene Expression," <i>Biochem. Biophys. Res. Comm.</i> 241:193-199 (December 1997)
	AT	2	Berglund, P. et al., "Alphaviruses as vectors for gene delivery," <i>TIBTECH</i> 14:130-134 (April 1996)

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PARADESHOCKET NO.
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FOREIGN PATENT DOCUMENTS

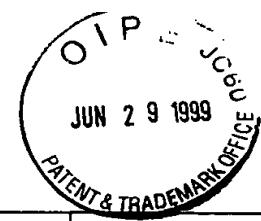
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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	3	Bohl, D. et al., "Long-term control of erythropoietin secretion by doxycycline in mice transplanted with engineered primary myoblasts," <i>Nature Med.</i> 3:299-305 (March 1997)
	AS	3	Bredenbeek, P. J. and C. M. Rice, "Animal RNA virus expression systems," <i>Seminars in Virol.</i> 3:297-310 (1992)
	AT	3	Bredenbeek, P. J. et al., "Sindbis Virus Expression Vectors: Packaging of RNA Replicons by Using Defective Helper RNAs," <i>J. Virol.</i> 67:6439-6446 (1993)

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		FILING DATE March 25, 1999	GROUP 1643

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	4	Burge, B. W. and E. R. Pfefferkorn, "Isolation and Characterization of Conditional-lethal Mutants of Sindbis Virus," <i>Virol.</i> 30:204-213 (1966)
	AS	4	Burge, B. W. and E. R. Pfefferkorn, "Complementation Between Temperature-sensitive Mutants of Sindbis Virus," <i>Virol.</i> 30:214-223 (1966)
	AT	4	Chapman, K. B. and J. W. Szostak, "Isolation of a ribozyme with 5'-5' ligate activity," <i>Chem. & Biol.</i> 2:325-333 (1995)

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APPLICATION NO.
09/275,883

APPLICANT
Renner et al.

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FOREIGN PATENT DOCUMENTS

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AL						Yes No
AM						Yes No
AN						Yes No
AO						Yes No
AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	5	Crameri, A. et al., "Improved Green Fluorescent Protein by Molecular Evolution Using DNA Shuffling," <i>Nature Biotech.</i> 14:315-319 (MARCH 1996)
AS	5	Davis, N. L. et al., "In Vitro Synthesis of Infectious Venezuelan Equine Encephalitis Virus RNA from a cDNA Clone: Analysis of a Viable Deletion Mutant," <i>Virol.</i> 171:189-204 (1989)
AT	5	De Groot, R. J. et al., "Sindbis virus RNA polymerase is degraded by the N-end rule pathway," <i>Proc. Natl. Acad. Sci. USA</i> 88:8967-8971 (1991)

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTACHMENT
FILE NUMBER
1780.0020001/JAG/SGW

APPLICATION NO.
09/275,883

APPLICANT
Renner et al.

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	6	Doedens, J. R. et al., "Inhibition of Endoplasmic Reticulum-to-Golgi Traffic by Poliovirus Protein 3A: Genetic and Ultrastructural Analysis," <i>J. Virol.</i> 71:9054-9064 (December 1997)
	AS	6	Dryga, S. A. et al., "Identification of Mutations in a Sindbis Virus Variant Able to Establish Persistent Infection in BHK Cells: The Importance of a Mutation in the nsP2 Gene," <i>Virol.</i> 228:74-83 (February 1997)
	AT	6	Dubensky, Jr., T. W. et al., "Sindbis Virus DNA-Based Expression Vectors: Utility for In Vitro and In Vivo Gene Transfer," <i>J. Virol.</i> 70:508-519 (January 1996)

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	Z	Dubuisson, J. et al., "Formation and Intracellular Localization of Hepatitis C Virus Envelope Glycoprotein Complexes Expressed by Recombinant Vaccinia and Sindbis Viruses," <i>J. Virol.</i> 68:6147-6160 (1994)
	AS	Z	Frolov, I. et al., "Alphavirus-based expression vectors: Strategies and applications," <i>Proc. Natl. Acad. Sci. USA</i> 93:11371-11377 (October 1996)
	AT	Z	Fröh, K. et al., "Displacement of housekeeping proteasome subunits by MHC-encoded LMPs: a newly discovered mechanism for modulating the multicatalytic proteinase complex," <i>EMBO J.</i> 13:3236-3244 (1994)

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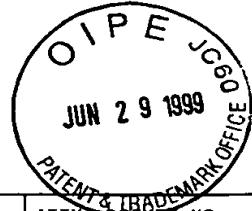
FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT		APPLICATION NO. 1700.0020001/JAG/SGW	
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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	8	Furth, P. A. et al., "Temporal control of gene expression in transgenic mice by a tetracycline-responsive promoter," <i>Proc. Natl. Acad. Sci. USA</i> 91:9302-9306 (1994)				
	AS	8	Gossen, M. and H. Bujard, "Tight control of gene expression in mammalian cells by tetracycline-responsive promoters," <i>Proc. Natl. Acad. Sci. USA</i> 89:5547-5551 (1992)				
	AT	8	Hahn, C. S. et al., "Infectious Sindbis virus transient expression vectors for studying antigen processing and presentation," <i>Proc. Natl. Acad. Sci. USA</i> 89:2679-2683 (1992)				

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	9	Hakimi, J. and P. H. Atkinson, "Glycosylation of Intracellular Sindbis Virus Glycoproteins," <i>Biochem.</i> 21:2140-2145 (1982)
	AS	9	Hariharan, M. J. et al., "DNA Immunization against Herpes Simplex Virus: Enhanced Efficacy Using a Sindbis Virus-Based Vector," <i>J. Virol.</i> 72:950-958 (February 1998)
	AT	9	Hennighausen, L. et al., "Conditional Gene Expression in Secretory Tissues and Skin of Transgenic Mice Using the MMTV-LTR and the Tetracycline Responsive System," <i>J. Cell. Biochem.</i> 59:463-472 (1995)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	10	Herweijer, H. et al., "A Plasmid-Based Self-Amplifying Sindbis Virus Vector," <i>Human Gene Ther.</i> 6:1161-1167 (1995)
	AS	10	Hoffmann, A. et al., "A novel tetracycline-dependent expression vector with low basal expression and potent regulatory properties in various mammalian cell lines," <i>Nucl. Acids Res.</i> 25:1078-1079 (March 1997)
	AT	10	Howe, J. R. et al., "The Responsiveness of a Tetracycline-sensitive Expression System Differs in Different Cell Lines," <i>J. Biol. Chem.</i> 270:14168-14174 (1995)

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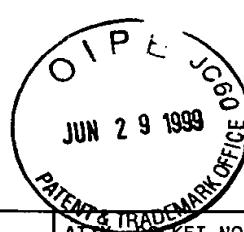
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	11	Huang, H. V., "Sindbis virus vectors for expression in animal cells," <i>Curr. Opin. Biotech.</i> 7:531-535 (October 1996)
	AS	11	Jeng, S.-Y. et al., "Characterization and Partial Purification of Bovine α -Lactalbumin and β -Casein Produced in Milk of Transgenic Mice," <i>J. Dairy Sci.</i> 80:3167-3175 (December 1997)
	AT	11	Johanning, F. W. et al., "A sindbis virus mRNA polynucleotide vector achieves prolonged and high level heterologous gene expression <i>in vivo</i> ," <i>Nucl. Acids Res.</i> 23:1495-1501 (1995)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	12	Kawamata, H. et al., "Induction of TSC-22 by treatment with a new anti-cancer drug, vesnarinone, in a human salivary gland cancer cell," <i>Brit. J. Cancer</i> 77:71-78 (January 1998)
	AS	12	Keränen, S. and L. Kääriäinen, "Functional Defects of RNA-Negative Temperature-Sensitive Mutants of Sindbis and Semliki Forest Viruses," <i>J. Virol.</i> 32:19-29 (1979)
	AT	12	Kerr, D. E. et al., "The bladder as a bioreactor: Urothelium production and secretion of growth hormone into urine," <i>Nature Biotech.</i> 16:75-79 (January 1998)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>13</u>	Kistner, A. et al., "Doxycycline-mediated quantitative and tissue-specific control of gene expression in transgenic mice," <i>Proc. Natl. Acad. Sci. USA</i> 93:10933-10938 (October 1996)
	AS	<u>13</u>	Lavrovsky, Y. et al., "Therapeutic Potential and Mechanism of Action of Oligonucleotides and Ribozymes," <i>Biochem. Mol. Med.</i> 62:11-22 (October 1997)
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APPLICATION NO.
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APPLICANT
Renner et al.

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GROUP
1643

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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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AM						Yes No
AN						Yes No
AO						Yes No
AP						Yes No

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	AR	<u>14</u>	Lee, K. H. et al., "Two-Dimensional Electrophoresis of Proteins as a Tool in the Metabolic Engineering of Cell Cycle Regulation," <i>Biotech. Bioengin.</i> 50:336-340 (May 1996)
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	AT	<u>14</u>	Lemm, J. A. et al., "Mutations Which Alter the Level or Structure of nsP4 Can Affect the Efficiency of Sindbis Virus Replication in a Host-Dependent Manner," <i>J. Virol.</i> 64:3001-3011 (1990)

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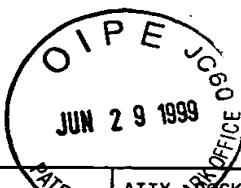
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	AR	16	Limonta, J. et al., "Production of active anti-CD6 mouse/human chimeric antibodies in the milk of transgenic mice," <i>Immunotech</i> . 1:107-113 (1995)
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	AR	<u>17</u>	Máthé, E. et al., "The <i>Tomaj</i> mutant alleles of α Tubulin67C reveal a requirement for the encoded maternal specific tubulin isoform in the sperm aster, the cleavage spindle apparatus and neurogenesis during embryonic development in <i>Drosophila</i> ," <i>J. Cell Sci.</i> 111:887-896 (April 1998)
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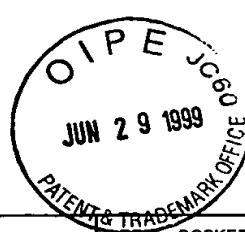
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	AM						Yes No
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	AR	<u>21</u>	Renner, W. A. et al., "Recombinant Cyclin E Expression Activates Proliferation and Obviates Surface Attachment of Chinese Hamster Ovary (CHO) Cells in Protein-Free Medium," <i>Biotech. Bioeng.</i> 47:476-482 (1995)
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	AT	<u>21</u>	Schlesinger, M. J. and S. Schlesinger, "Formation and Assembly of Alphavirus Glycoproteins," in <i>The Togaviridae and Flaviviridae</i> , Plenum Press, New York, NY, pp. 121-148 (1986)

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AN							Yes No
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>22</u>	Schlesinger, S., "Alphaviruses - vectors for the expression of heterologous genes," <i>TIBTECH</i> 11:18-22 (1993)
	AS	<u>22</u>	Shockett, P. et al., "A modified tetracycline-regulated system provides autoregulatory, inducible gene expression in cultured cells and transgenic mice," <i>Proc. Natl. Acad. Sci. USA</i> 92:6522-6526 (1995)
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AN							Yes No
AO							Yes No
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	AR	<u>23</u>	Schwer, B. et al., "Effects of deletion mutations in the yeast Ces1 protein on cell growth and morphology and on high copy suppression of mutations in mRNA capping enzyme and translation initiation factor 4A," <i>Nucl. Acids Res.</i> 26:803-809 (February 1998)
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	AT	<u>23</u>	Stanley, P., "Glycosylation engineering," <i>Glycobiology</i> 2:99-107 (1992)

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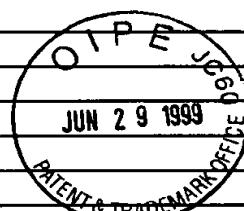
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	AR	25	Wang, Y. et al., "A regulatory system for use in gene transfer," Proc. Natl. Acad. Sci. USA 91:8180-8184 (1994)
	AS	25	Wang, Y. et al., "Ligand-inducible and liver-specific target gene expression in transgenic mice," Nature Biotech. 15:239-243 (March 1997)
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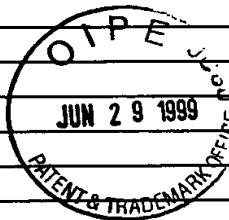
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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 1700.0020001/JAG/SGW		APPLICATION NO. 09/275,883	
		APPLICANT Renner <i>et al.</i>			
		FILING DATE March 25, 1999		GROUP 1643	

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA							
AB							
AC							
AD							
AE							
AF							
AG							
AH							
AI							
AJ							
AK							

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL							Yes No
AM							Yes No
AN							Yes No
AO							Yes No
AP							Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	28	Zang, M. <i>et al.</i> , "Production of Recombinant Proteins in Chinese Hamster Ovary Cells Using a Protein-Free Cell Culture Medium," <i>Biotech.</i> 13:389-392 (1995)
AS	AS	28	Invitrogen Manual, "Sindbis Expression System, Version C," from internet web page http://www.invitrogen.com/manuals.html , Catalog No. K750-01 (1996)
	AT		

EXAMINER	DATE CONSIDERED
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